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Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Division Manager,

Please find enclosed our General Comments as requested in the December 31, 2003 Federal Register, 68 Fed Reg 75585, 7786. Specifically, we are writing with regards to Docket No. 2003N-0539, and the FDA's request for information regarding the designation of Vaginal Lubricants as Over-the-Counter drugs.

The authors of these comments do not agree that vaginal lubricants and moisturizers require an OTC drug monograph for safe and appropriate usage. However, existing labels on lubricants and vaginal moisturizers bear claims regarding their effect on sperm which are inadvertently misleading and may be resulting in significant Public Health risks for couples actively trying to conceive children. The following comments address the need for clear testing of sperm function for, and subsequent labeling of, any genitally applied lubricant or moisturizer used by couples during intercourse for procreation.

At least 11 million couples in the United States are actively seeking to conceive a child. Six million of these couples are "infertile", meaning they have been trying to conceive for over one year without a successful pregnancy. Costs of medical intervention for these couples exceed \$2 B/ year in the US, with much of this paid directly by couples due to limited health insurance coverage for infertility.


These trying-to-conceive (TTC) couples have a high incidence of vaginal dryness affecting their sexual function. In fact, 75% of TTC couples have reported an increased incidence of personal dryness due to having timed intercourse around ovulation, fertility medications and fear of failure. Unfortunately, three decades of peer reviewed and published research has shown that existing vaginal lubricants harm sperm.

The authors of these studies have stated that the use of vaginal lubricants is **contraindicated** in subfertile couples, particularly those 60% of infertile couples with male factor (or sperm) issues. In spite of these reports, there remains a great deal of confusion amongst physicians and lay people alike as to the safety of vaginal lubricant use while trying to become pregnant.

In order to clarify confusion amongst medical professionals and consumers, vaginal lubricants that deleteriously affect sperm function as determined by repeatable, standard assays should incorporate warning labels stating that they are unsafe for use while trying to conceive. Minimum levels of sperm function following contact with vaginal lubricants should be developed and included in labeling to protect couples that are trying to conceive. The following Comments review the literature and public health impact of vaginal lubricant use by couples seeking to conceive children; provide suggestions for testing of sperm function during contact with these products; and propose suggested labeling for appropriate consumer and medical community use.

Sincerely,


JE Ellington PhD
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2003N-0539

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**GENERAL COMMENTS ON DOCKET No. 2003N-0539
OTC DESIGNATION FOR VAGINAL LUBRICANTS**

***Need for improved labeling for use of vaginal lubricants
by
trying-to-conceive couples***

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